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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,985	09/15/2005	Karl Lintner	SEDERM3.3-011	4999

530 7590 12/28/2006  
LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

EXAMINER
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AULAKH, CHARANJIT

ART UNIT	PAPER NUMBER
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1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,985	<b>Applicant(s)</b> LINTNER, KARL	
	<b>Examiner</b> Charanjit S. Aulakh	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. According to paper filed on Oct. 6, 2006, the applicants have canceled claims 18-21; amended claims 22-38 and furthermore, have added new claims 39-55.
2. Claims 22-55 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on Oct. 6, 2006 have been fully considered but they are not persuasive regarding enablement rejection, some indefiniteness rejections and most of the prior art rejections. In regard to enablement rejection for making and using the instant compounds alone or in combination with other active agents, the examiner does not agree with the applicant's arguments that the specification is enabling for making instant compounds of formula I based on synthesis of only one compound in instant example 1. There is no teaching or direction provided regarding synthesis of any other compound besides a single compound. The examiner also does not agree with the applicants arguments that the specification is enabling for using the instant compounds either alone or in combination with hundreds of thousands of other active agents such as antitumor compounds, antibiotics, cytotoxic agents etc. for the intended purpose. As stated clearly in the last office action, the instant specification teaches only preparing a single compound and all the in vitro experimental data shown in the instant specification is using this single compound only. There is no teaching or guidance provided or any experimental data presented to show that the combination of even this single compound with other active agents such as antitumor agents will actually maintain its efficacy in the in vitro experiments mentioned in the instant specification.

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In regard to indefiniteness rejections of instant claims 22, 26, 29-32 and 34-38, the examiner does not agree with the applicants arguments regarding definiteness of the terms --- active substances, inorganic support and plant extract ---. The applicants are suggested to include specific substances, active agents and plant extract which are enabled by the instant specification.

In regard to prior art rejections over Su's reference ( U.S.Patent 6,313, 134 ), Krell's reference ( WO 99/16441 ) and Maasbol's reference ( U.S. Patent 4,279, 914 ), the examiner does not agree with the applicant's arguments that these references do not anticipate the instant pharmaceutical composition claims. The applicants have amended claims to include the word, topical to overcome these references. However, first of all, this term introduces new matter as will be discussed later and furthermore, the amended claims are still directed to a pharmaceutical composition and not method claims and therefore, do anticipate the instant pharmaceutical composition claims.

### ***Conclusion***

4. Rejection of claims 22-38 as well as of newly submitted claims 39-55 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejection of claims 22, 26, 29-32, 34-38 as well of newly submitted claims 39-55 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. Rejection of claims 22-36 as well as of newly submitted claims 47 and 49-55 under 35 U.S.C. 102(a) over Su's reference is maintained for the reasons of record.
7. Rejection of claims 22-36 as well as of newly submitted claims 47, 48 and 50-55 under 35 U.S.C. 102(b) over Krell's reference is maintained for the reasons of record.

8. Rejection of claims 22, 24-36 and newly submitted claims 47 and 50-55 under 35 U.S.C. 102(b) over Maasbol's reference is maintained for the reasons of record.

NEW GROUNDS OF REJECTION

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 22-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicants have amended claims to insert the term –topical ---. This term introduces new matter since this term is not mentioned or described in the original specification.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claim 55 is rejected under 35 U.S.C. 102(a) as being anticipated by Pauly ( EP 1145709).

Pauly discloses natural products for cosmetic compositions. The cosmetic composition comprising Boldine anticipates the instant claim when R1 and R4 represent –OH while R2, R3 and R5 all represent methyl group in the instant compounds of formula I.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

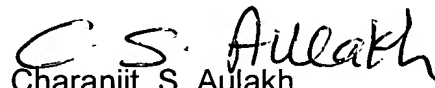
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625